K131137
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JVC KENWOOD

JUL 18 2013

510(k) SUMMARY

Submitted Information:	JVC KENWOOD Corporation 3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi, Kanagawa, 221-0022 Japan
Contact Person:	Tsukasa Tashiro, General Manager Email: tashiro.tsukasa@jvckenwood.com Tel: +81.258.24.6611 Fax: +81.258.24.6617
Date Prepared:	July 17, 2013
Device Name:	21.3 inch Monochrome Digital Mammography LCD Monitor MS55i2 (ML21055, MD211G5)
Common Name:	MS55i2, ML21055, MD211G5
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	21.3 inch (54 cm) Monochrome Digital Mammography LCD Monitor MS53i2 (ML21053) (K111496).
Device Description:	MS55i2 (ML21055, MD211G5) is a 21.3-inch monochrome LCD monitor whose display resolution is 2048 x 2560 (landscape), 2560 x 2048 (portrait) supporting DVI (digital visual interface) and DisplayPort.
Intended Use:	21.3 inch Monochrome Digital Mammography 5M pixel LCD Monitor with sub-pixel driving techniques enabling 15M subpixels to be driven independently, MS55i2 (ML21055, MD211G5) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is to be used in digital mammography PACS and modalities including FFDM.
Substantial Equivalence:	MS55i2 (ML21055, MD211G5) shares the same characteristics with our predicate device MS53i2 (ML21053) (K111496) except for the main board, LCD panel and power supply.

Substantial Equivalence Comparison

	5M Monochrome Digital Mammography LCD Monitor MS53i2 (ML21053) (K111496) **Conventional LCD Panel (IAQS80P)**	**5M Monochrome Digital Mammography LCD Monitor MS55i2 (ML21055, MD211G5) New LCD Panel (TX54D84MM0BAA)**
510(k) Number	K061447	Not Known
Display Area	Horizontal: 337.9mm, Vertical: 422.4mm	Horizontal: 337.92mm, Vertical: 422.4mm
Input Signal	DVI, DisplayPort	DVI, DisplayPort
Maximum Display	2048 x 2560 dots	2048 x 2560 dots
Scanning Frequency	Horizontal: 129.6K, Vertical: 50Hz - Portrait Horizontal: 103.93KHz, Vertical: 50Hz - Landscape	Horizontal: 129.6K, Vertical: 50Hz - Portrait Horizontal: 103.5KHz, Vertical: 50Hz - Landscape
Maximum Image Clock	148 MHz	285 MHz
Maximum Luminance (Calibrated Luminance)	Min.850 cd/m^2 Typ.1100cd/ m^2 (500 cd / m^2 - calibrated luminance)	Min.850 cd/m^2 Typ.1200cd/ m^2 (as LCD component) (500 cd / m^2 - calibrated luminance)
Contrast Ratio	Min.600 Typ.850	Min.900 Typ.1200
Viewing Angle	CR>20 Typ.85deg	CR>50 Typ.176 horizontal/vertical
Luminance Calibration (Optional)	Software (Standard): Medivisor Calibration Sensor (Optional): Chroma5 (X-Rite)	Software (Standard): Medivisor Calibration Sensor (Optional): Chroma5 (X-Rite)
Serial Communication	USB: Downstream port x 2, Upstream port x 1	USB: Downstream port x 2, Upstream port x 1
Grayscale	10.3 bit (1276 gradation)	10.3 bit (1276 gradation)
Safety Standard	UL60601-1, CSA C22.2 No. 601-1, FCC-B, VCCI-B, MDD/CE,	UL60601-1, CSA C22.2 No. 601-1, FCC-B, VCCI-B, MDD/CE,
Weight & Dimension	Net: 12.1kg 474.5(W) x 480(H) x 220(D) mm (Landscape) 389(w) x 522(H) x 220(D) mm (Portrait) Packed: 17.0 Kg 470(W) x 685 (H) x 345(D)	Net: approx.12.8kg 474.5(W) x 480(H) x 220(D) mm (Landscape) 390(w) x 522(H) x 220(D) mm (Portrait) Packed: approx.16.0 Kg 470(W) x 685 (H) x 345(D)
Power Supply	AC100-240V, 1.5-0.6A, 50/60Hz	AC100-240V, 1.5-0.6A, 50/60Hz

Similarities:

MS55i2 (ML21055) employs the same driver board, tilt stand, power supply, etc. except of those of LCD Panel (included inverter board).

Differences:

MS55i2 (ML21055) employs a different LCD panel (LED backlight) and the Maximum Luminance, contrast ratio and viewing angle have been improved. MD211G5 is the same as MS55i2 only tilt stand differing.

Display System Description

1. Active-Matrix Liquid-Crystal Displays (AMLCD) panel manufacturer, technologyScreen size and pixel pitch:
   Screen size: 422.4mm(H) x 337.92mm(V) at landscape display. 337.92mm(H) x 422.4mm(V) at portrait display. Pixel pitch: 0.055mm(H) (sub-pixel pitch) x 0.165mm(V) at landscape display. 0.165mm(H) x 0.055mm(V) (sub-pixel pitch) at portrait display
   • Communicating ports:
     Serial communication: USB (upstream x1, downstream x2)
2. Graphics card and software
   • Digital-to-Analog converters: speed and precision:
     Only Digital operation, Digital to Analog converters are not provided.
   • Software included: calibration, QC/QA (procedures with required frequencies and action limits):
     Totoku's calibration software called "Mediviser" optimizes the display's performance using DICOM GSDF gamma and luminance. Calibration is recommended quarterly.
   • On-screen GUI: On-screen GUI is not provided.
   • Panel user controls: power switch

Technical Specification

1. Measuring Equipment
   Refer to List
2. Declared and actual (measured with test pattern in the screen) array size:
   Declared array size (spec): 422.4mm(H) x 337.92mm(V)
   Actual array size (measured): 422.35mm(H) x 337.95mm(V)
3. Luminance response
   • max and min achievable luminance:
     [SPEC] Luminance Max (Lmax)=1200cd/m2. Luminance Min (Lmin)= 0.5cd/m2
   • max and min recommended (operational) luminance:
     [SPEC] Luminance Max recommend: Lmax(r)=500cd/m2. Lmin(r)=0.8cd/m2
   • intrinsic bit-depth of the panel: [SPEC] 8bit per each subpixel
   • true output bit-depth by performing visual test with gradient test pattern:
     [SPEC] 10.3bit grayscale (1276 steps) achieved by 11bit LUT (Look-up Table) in the Display hardware.
   • intrinsic luminance response at 256 digital values:
     [SPEC] dJND per dP<3.000, dJNDs/dP max error<2.000.
     JNDs/P RMS error<1.000
     Above spec is based on AAPM-TG18 Advanced Luminance Response. 4.3.5
     Refer to actual luminance response data
   • conformance to a grayscale function (i.e., DICOM GSDF) at 256 digital values and angular dependence of such conformance:
     [SPEC] K6 within +/- 10% deviation to DICOM GSDF based on AAPM-TG18 Luminance Response 4.3.4
     Refer to actual luminance response data including angular dependence (Digital Driving Level vs Delta L.L)
   • angular dependency o_f luminance:
     [SPEC] LR>175, K6<30%
4. Luminance uniformity
   [SPEC] Less than 30% based on AAPM-TG18 4.4. Refer to actual Luminance uniformity data

5. Geometrical distortion
[SPEC] Less than 2.0% based on AAPM-TG18. Refer to actual Geometrical Distortion data

6. Display reflectance
- Bi-directional reflection distribution function, or
- specular and diffuse coefficients (ISO13406-2 by TUV)

[SPEC] Refer to Max allowable ambient luminance in Tables 4 and 5 on AAPM-TG18 4.2.4
Refer to actual Reflectance Data

7. Noise
- Pixel fill factor (fefxos ISO13406-2)

[SPEC] 30% Min. Refer to Data of Pixel fill factor.
- RMS (image variance) and noise power spectrum (weiner spectrum)

[SPEC] 0.1 Max at 0.6Hz, 5Hz, 30Hz Jitter. Refer to actual data

8. Veiling glare
[SPEC] Glare Ratio (GR) ≥ 400 GR (Lb-Ln)/(L-Ln) based on AAPM-TG18 4.7.4
Refer to actual veiling glare ratio data

9. Chromaticity
[SPEC] Delta (u', v') ≤ 0.01 measured at 80% Lmax based on AAPM-TG18 4.8.4
Refer to Chromaticity actual data

10. Artifacts
- pixel dropouts including spatial distribution (ISO13406-2 by TUV):

[SPEC] Class (pixel) II. Refer to table 3 on 3.4.13 ISO13406-2
- phase/clock issues flicker
- miscellaneous including ringing, ghosting, image sticking

[SPEC] By visible check, no ringing, ghosting image sticking

11. Spatial resolution, spatial MTF
[DATA] Refer to actual MTF data

12. Temporal response
- Temporal MTF, or
- rise and fall time constants for 5-95% and 40-60% transitions by CMO.

[SPEC] Rise Time Tr, Fall Time Tf, Tr, Tf≤55mS. Refer to actual data

13. Stability (possibly determined via temperature or time stress tests) by TUV
- of luminance response, of temporal response, of described artifacts

[SPEC] Kδ within +/- 10% deviation to DICOM GSDF, based on AAPM-TG18 Luminance Response 4.3.4 via temperature stress 0 degC, 25degC, 40degC
Refer to actual measured data

[fefxos = for example, following … or similar]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2013

JVC KENWOOD Corporation
% Mr. Tsukasa Tashiro
General Manager
3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi
Kanagawa 221-0022
JAPAN

Re: K131137
Trade/Device Name: 21.3 inch Monochrome Digital Mammography LCD Monitor MS55i2 (ML21055, MD211G5)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 19, 2013
Received: April 23, 2013

Dear Mr. Tashiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

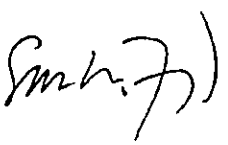
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131137

Device Name: 21.3 inch Monochrome Digital Mammography LCD Monitor MS55i2 (ML21055, MD211G5)

Indications for Use:

21.3 inch Monochrome Digital Mammography 5M pixel LCD Monitor with sub-pixel driving techniques enabling 15M subpixels to be driven independently. MS55i2 (ML21055, MD211G5) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is to be used in digital mammography PACS and modalities including FFDM.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131137